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510(k) Summary for Dosimetry Check Version 4 Release 1

Submitter's Name	Math Resolutions, LLC
Address	5975 Gales Lane Columbia, MD USA 21045
Establishment Registration Number	1833314
Date of Summary	September 17, 2013
Telephone Number	(410) 997-9578
Email	WDRenner@MathResolutions.com
Contact Person	Wendel Dean Renner
Name of the Device	Dosimetry Check version 4 release 1
Common or Usual Name	Standalone Software Quality Control System
Classification Name	Quality Control for Medical Charged-particle Radiation Therapy Systems. 21 CFR 892.5050
Indications for Use	Dosimetry Check is a standalone software product intended to be used by an experienced radiological physicist for quality control purposes only. Dosimetry Check is intended to check the correctness of x-ray treatment plans delivered from high energy charged-particle radiation therapy treatment machines by using a measurement of the applied radiation fields that are planned to be or have been applied to a patient, and computing the dose to the patient from the measured radiation fields. This product is to be used as a quality control check for the treatment planning system and delivery system. Dosimetry Check quality control software uses the radiation fields that are measured with media such as x-ray film, electronic portal imaging devices (EPID), diode or ion chamber arrays, or in the case of TomoTherapy, a fan line detector array, and provides a theoretical calculation. Dosimetry Check computes the dose and dose distribution using the patient specific CT or other image set or alternately a phantom that is likewise scanned, to calculate the reconstructed dose that is then compared to the plan dose. The results reported can include the computed percent difference at specific points as compared to the patient specific radiation treatment plan. Dosimetry Check does not provide any conclusions regarding the comparisons and does not provide any criteria to be used for interpreting the results. The experienced radiological physicist can reevaluate his patient specific radiation treatment plan in accordance with his clinical judgment.

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510(k) Summary continued

Indications for Use cont.	This product is not a treatment planning system and is not to be used as one. This product only checks the applied dose based on the measurement of each x-ray field applied to the patient and provided in an exported file, and a theoretical calculation. This product does not provide any quality assurance that the fields are in fact correctly applied to and correctly aligned with the patient anatomy as planned. In addition, the product may be used to display the above dose on other fused image sets which could provide additional supportive quality information to the user regarding the correctness of treatment.
Identification of the Legally Marketed Device (Predicate Device	**Dosimetry Check version 3 release 1, K101503**
Device Description	System 2100 for which 510(k) K993530 was cleared by the FDA on December 15, 1999 that is a medical image display system serves as a foundation that provides basic image display functionality for Dosimetry Check. Dosimetry Check is a software program that will compute the dose and dose distribution to the patient from a measurement of the radiation fields that are applied to the patient. The dose so computed serves as a means to verify the correctness of the radiation treatment and to serve as a final sanity check. The radiation fields are measured with media such as x-ray film or electronic devices that will measure over the area of the field, such as electronic portal imaging devices (EPID), or diode or ion chamber arrays. To extend Dosmetry Check to support the TomoTherapy machine, the device uses the data measured by the fan beam radiation detector that is part of the TomoTherapy machine. The detectors capture the radiation intensity periodically at predetermined gantry angles and couch positions, known as control points, from the treatment plan. The detector only measures the intensity across the center of the radiation beam in the transverse plane. A prior measured profile in the perpendicular longitudinal direction is then applied to complete the radiation field map. The radiation field map is then applied as a stationary beam at the center gantry angle and couch position for the integration period (between two control points), from which the dose to the patient is computed. The patient dose is then summed up from all such radiation field maps.

Intended Use for Predicate Device: Dosimetry Check version 3 release 1
Dosimetry Check with Exit Dose is a software program intended to provide a means for testing the dosimetry of radiation therapy treatments applied to a patient using high energy x-rays. This test is performed from measurements made during treatment of the patient by measuring the radiation fields after they have passed through the patient with a suitable imaging device such as an electronic portal imaging device or other measuring devices or media. The following software functions are then performed:

1. The patient's CT scan treatment plan image set is traced to provide the water equivalent path to points on the measured exit dose plane.
2. A deconvolution process is performed with a kernel that is a function of radius and the thickness transversed to convert the exit images back to x-ray intensity in air fluence prior to patient entry. The kernel is derived prior from phantom measurements with the same imaging device or media.
3. The derived in air fluence is now the same starting point as when the radiation fields are measured directly prior to patient entry.

Intended Use for Modified Device: Dosimetry Check version 4 release 1
Dosimetry Check is a standalone software product intended to be used by an experienced radiological physicist for quality control purposes only. Dosimetry Check is intended to check the correctness of x-ray treatment plans delivered from high energy charged-particle radiation therapy treatment machines by using a measurement of the applied radiation fields that are planned to be or have been applied to a patient, and computing the dose to the patient from the measured radiation fields. This product is to be used as a quality control check for the treatment planning system and delivery system.

Dosimetry Check quality control software uses the radiation fields that are measured with media such as x-ray film, electronic portal imaging devices (EPID), diode or ion chamber arrays, or in the case of TomoTherapy, a fan line detector array, and provides a theoretical calculation. Dosimetry Check computes the dose and dose distribution using the patient specific CT or other image set or alternately a phantom that is likewise scanned, to calculate the reconstructed dose that is then compared to the plan dose. The results reported can include the computed percent difference at specific points as compared to the patient specific radiation treatment plan.

Dosimetry Check does not provide any conclusions regarding the comparisons and does not provide any criteria to be used for interpreting the results. The experienced radiological physicist can reevaluate his patient specific radiation treatment plan in accordance with his clinical judgment.

This product is not a treatment planning system and is not to be used as one. This product only checks the applied dose based on the measurement of each x-ray field applied to the patient and provided in an exported file, and a theoretical calculation. This product does not provide any quality assurance that the fields are in fact correctly applied to and correctly aligned with the patient anatomy as planned. In addition, the product may be used to display the above dose on other fused image sets which could provide additional supportive quality information to the user regarding the correctness of treatment.

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Device Comparison Table

Features	**Predicate** Dosimetry Check version 3 release 1 **K101503**	**Modified Device** Dosimetry Check version 4 release 1 **K132605**
Pre-treatment images	Yes	Yes
Exit images	Yes	Yes
Compute dose to patient	Yes	Yes
Compare to planning system dose	Yes	Yes
Used for verifying the correctness of radiation therapy treatments	Yes	Yes
Uses a line in the transverse plane through the radiation field measurement provided to Dosimetry Check. A prior measured longitudinal profile is applied to each detector signal to complete the radiation field.	No	Yes
Generates a report as described in the Dosimetry Check manual using either the auto-report feature, or the user may construct their own report using the evaluate tools.	Yes	Yes
Installed by downloading the software from the Math Resolutions web site at http://www.mathresolutions.com/downlprg.htm	Yes	Yes
Photons (x-ray)	Yes	Yes
Electrons	No	No
Protons	No	No
Ability to use the TomoTherapy detector data measured in a pretreatment dry run without the patient and the detector data taken during treatment	No	Yes
Operating Systems	Microsoft Windows XP, Windows Vista, Windows 7, and Ubuntu 9.04 (Linux)	Microsoft Windows XP, Windows Vista, Windows 7, and Ubuntu 9.04 (Linux)
Hardware needed but not provided	Open GL capable graphics card is required with 24 true.color and a depth buffer. For added stereoscoptic three dimensional displays, an Nvidia Quadro fx card that supports stereo is needed with a single monitor capable of 120 Hertz refresh rate or the Planar Mirror System with two monitors.	Open GL capable graphics card is required with 24 true color and a depth buffer. For added stereoscoptic three dimensional displays, an Nvidia Quadro fx card that supports stereo is needed with a single monitor capable of 120 Hertz refresh rate or the Planar Mirror System with two monitors.

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Description and Conclusion of Testing	**Nonclinical Testing:** Nonclinical testing included modular testing, regression testing, verification of the risk control measures implemented in the software, verification of successful installation and performance testing. **External Validation:** The external validation was performed at two (2) sites in Europe, three (3) sites in the US. All aspects of using Dosimetry Check for quality control for TomoTherapy were tested during the beta testing. The conclusions of the beta test results submitted demonstrated the safety and performance of the Dosimetry Check software for its intended use and that it can be used by its intended users to compute the dose from the TomoTherapy detector as a quality tool for radiation treatments on that machine. **Conclusion:** The successful non-clinical testing and external validation demonstrates the safety and effectiveness of the Dosimetry Check Version 4 Release 1 when used for the defined indications for use and demonstrates that the device for which this 510(k) is submitted performs as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Math Resolutions, LLC
% Mr. Wendel Dean Renner
President
5975 Gales Lane
COLUMBIA MD 21045

November 14, 2013

Re: K132605
Trade/Device Name: Dosimetry Check Version 4 Release 1
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: Sep. 17, 2013
Received: Sep. 24, 2013

Dear Mr. Renner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132605

Device Name: Dosimetry Check Version 4 Release 1

Indications for Use:

Dosimetry Check is a standalone software product intended to be used by an experienced radiological physicist for quality control purposes only. Dosimetry Check is intended to check the correctness of x-ray treatment plans delivered from high energy charged-particle radiation therapy treatment machines by using a measurement of the applied radiation fields that are planned to be or have been applied to a patient, and computing the dose to the patient from the measured radiation fields. This product is to be used as a quality control check for the treatment planning system and delivery system.

Dosimetry Check quality control software uses the radiation fields that are measured with media such as x-ray film, electronic portal imaging devices (EPID), diode or ion chamber arrays, or in the case of TomoTherapy, a fan line detector array, and provides a theoretical calculation. Dosimetry Check computes the dose and dose distribution using the patient specific computed tomography (CT) or other image set or alternately a phantom that is likewise scanned, to calculate the reconstructed dose that is then compared to the plan dose. The results reported can include the computed percent difference at specific point as compared to the patient specific radiation treatment plan.

This product is not a treatment planning system and is not to be used as one. This product only checks the applied dose based on the measurement of each x-ray field applied to the patient and provided in an exported file, and a theoretical calculation. This product does not provide any quality assurance that the fields are in fact correctly applied to and correctly aligned with the patient anatomy as planned. In addition, the product may be used to display the above dose on other fused image sets which could provide additional supportive quality information to the user regarding the correctness of treatment.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign-off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health (OIR)
510(k) K132605